IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **ALL PLAINTIFFS LISTED IN PLAINTIFFS' MOTION**	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE GENERAL OPINION TESTIMONY OF DR. GREGORY T. BALES, M.D.

Gregory T. Bales, M.D. is a board-certified urologist who has performed over 1,000 pelvic floor surgeries, placed over 1,000 midurethral slings, and treated mesh complications. Dr. Bales also has published on the technique of mesh implants and the treatment of complications.

Despite this extensive career, Plaintiffs seek to exclude Dr. Bales's opinions regarding: (1) the recurrence rate for native tissue surgical procedures; (2) whether dyspareunia is a risk of Prolift and Gynemesh devices; (3) clinical consequences of mesh shrinkage; (4) the biocompatibility properties of pelvic mesh; (5) the warnings for Prolift and Gynemesh devices; and (6) potential trial testimony that may be contrary to Dr. Bales's deposition testimony (or Plaintiffs' view thereof). Plaintiffs' motion should be denied because:

- **Dr. Bales's opinions are supported by a reliable methodology**. Relying on training, clinical experience, and review of the relevant medical literature is a reliable method for forming opinions on complication rates, the risks associated with mesh devices, and the clinical consequences of mesh shrinkage.

- **Dr. Bales is qualified to offer the challenged opinions.** Dr. Bales's extensive clinical and research background make him well qualified to give opinions on the biocompatibility properties of pelvic mesh, as well as Ethicon's Instructions for Use (IFU).

- **Concerns about potential inconsistencies are not a basis to exclude expert testimony.** It is well-established that, if any inconsistencies in expert testimony later arise, such inconsistencies should be addressed during cross examination.

Plaintiffs' challenges to Dr. Bales's opinion testimony are meritless under Rule 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). At bottom, Plaintiffs simply disagree with Dr. Bales's conclusions. This is no basis for exclusion under *Daubert*. Defendants Ethicon, Inc. and Johnson & Johnson (Ethicon) therefore ask that Plaintiffs' motion be denied.

ARGUMENT AND AUTHORITIES

I. Dr. Bales's Opinion on the Recurrence Rate of Native Tissue Surgical Procedures Is Admissible Because He Utilized a Reliable Methodology.

A physician's "knowledge, experience, and review of scientific literature provide sufficiently reliable bases for his opinions under *Daubert*." *Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 714 (S.D.W. Va. 2014). An expert may opine on complications rates based on personal experience and review of medical literature. *See id.* (denying request to exclude Dr. Walmsley's general opinions on complication rates based on his personal clinical experience and review of the medical literature).

Dr. Bales used this scientifically reliable methodology here. He relied upon his extensive surgical experience, knowledge, training, research, and analysis of the relevant medical literature to reach his opinions. *See generally* Ex. D to Pls.' Mot. (Dkt. 2054-5), Bales CV; Ex. 1, Reliance List. Specifically, Dr. Bales is a board-certified urologist, Professor of Surgery/Urology and the Director of Female and Pelvic Reconstruction and Neurourology at the University of Chicago School of Medicine. Ex. 2, Bales 4/1/16 Dep. Tr. 44: 1-4; Ex. D to Pls.' Mot. (Dkt. 2054-5), Bales CV at 2, 25. He has performed over 1,000 pelvic floor surgeries, both with and without mesh, including hundreds of procedures using Prolift. Ex. 2, Bales 4/1/16 Dep. Tr. 30:2-5, 31:21-

32:4. He has evaluated and treated patients for a variety of complications involving pelvic procedures with and without mesh. *Id.* at 32:19-33:24.

Dr. Bales has been published approximately 65 times, with several of those publications detailing the technique of mesh implants and the treatment of complications. *See* Ex. 2, Bales 4/1/16 Dep. Tr. 32:5-13; Ex. D to Pls.' Mot. (Dkt. 2054-5), Bales CV at 3-12. Dr. Bales has written several book chapters, including one on complications of mid-urethral mesh sling surgery. *See* Ex. D to Pls.' Mot. (Dkt. 2054-5), Bales CV at 7-8.

In addition, Dr. Bales reviewed a "broad array of Level 1 evidence that reflects good science" in reaching his opinions here. Ex. 2, Bales 4/1/16 Dep. Tr. 12:15-23; *see also* Ex. 1, Reliance List. In particular, Dr. Bales concludes that the recurrence rate exceeds 30 percent for colporrhaphy particularly in the anterior compartment, citing three supporting studies. Ex. A-1 to Pls.' Mot. (Dkt. 2054-2), Bales Report at 4 & n. 3. Dr. Bales further testified that the failure rate of native tissue posterior repairs is 20 to 30 percent. Ex. 2, Bales 4/1/16 Dep. Tr. 53:17-54:15. When questioned about different recurrence rates, Dr. Bales explained that he had concluded a "30 percent [recurrence rate] is a more accurate representation of what the experience is nationwide" with regard to native tissue surgical procedures. *Id.* at 67:3-5.

Plaintiffs are incorrect that Dr. Bales ignored contrary literature concerning his opinion about the recurrence rate for certain native tissue repairs. As to the 2011 Weber article, Dr. Bales testified twice that he considered the information in this article. *Id.* at 61:4-6, 63:13-19. Similarly, Dr. Bales testified to his familiarity with what Plaintiffs refer to as the "study from 2013" (Pls.' Mem. (Dkt. 2057) at 7) and the "important study" (*id.*), in addition to other articles raised by Plaintiffs' counsel at Dr. Bales's deposition. *See* Ex. 2, Bales 4/1/16 Dep. Tr. 67:21-23 (paper by Funk and Visco), 68:18-20 (paper by Dr. Oversand), 69:16-21 (paper on Dr. Iglesia's

original Prolift study). Rather than ignore these articles, however, Dr. Bales testified to the effect that they were "anomalies," inconsistent with the bulk of the literature showing higher recurrence rates. *See*, *e.g.*, Ex. 2, Bales 4/1/16 Dep. Tr. 63:13-19.

In any event, while Plaintiffs' assertions may be points for cross examination, they do not lead to exclusion of Dr. Bales's opinion. This Court has held that an expert's reasons for rejecting scientific studies should be addressed on cross-examination. *See Wilkerson v. Boston Scientific Corp.*, No. 2:13-CV-04505, 2015 WL 2087048, at *10 (S.D.W. Va. May 5, 2015) ("Whether [the expert's] reasons for rejecting certain studies are accurate or whether [the expert] inconsistently applies these reasons to the literature are appropriate topics for cross-examination."); *see also Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."). Similarly, Plaintiffs' accusation that Dr. Bales is "biased" goes to the weight of his opinions, not their admissibility. *Sanchez v. Boston Scientific Corp.*, No. 2:12-CV-05762, 2014 WL 4851989, at *29 (S.D.W. Va. Sept. 29, 2014), reconsideration denied, No. 2:12-CV-05762, 2014 WL 5320559 (S.D.W. Va. Oct. 17, 2014) ("If the plaintiffs take issue with Dr. Mays's failure to review or cite particular documents, this goes to the weight of his opinion, not its admissibility, and can be addressed on cross-examination.").

Dr. Bales has provided a reliable basis for his opinion on the complication rate of native tissue surgical procedures. The arguments raised by Plaintiffs are appropriately addressed during cross-examination and do not support exclusion of Dr. Bales's testimony.

II. Dr. Bales's Opinion on the Risks of Prolift and Gynemesh Devices Is Admissible Because He Utilized a Reliable Methodology.

This Court has made clear that a physician can draw upon his clinical experience and review of relevant literature to give an opinion on the risks and benefits of polypropylene mesh. *Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *7 (S.D.W. Va. Apr. 24, 2015). Dr. Bales seeks to do so here. Based on his training, experience, and review of the relevant medical literature, Dr. Bales concluded dyspareunia is not a risk that is unique to the Prolift and Gynemesh devices. Ex. A-1 to Pls.' Mot. (Dkt. 2054-2), Bales Report at 8; Ex. 2, Bales 4/1/16 Dep. Tr. 102:12-103:12, 104:16-105:11. Specifically, Dr. Bales opined that "[d]yspareunia is a long-standing, well-known complication that is well established in the surgical literature regarding the surgical repair of POP." Ex. A-1 to Pls.' Mot. (Dkt. 2054-2), Bales Report at 8. Dr. Bales further concluded that "[o]verall, the studies comparing Prolift to native tissue repairs do not show any statistically significant differences in rates of de novo dyspareunia, pelvic pain or sexual dysfunction," citing four literature sources for support. *Id*. Dr. Bales therefore determined that dyspareunia is a risk of pelvic organ prolapse (POP) surgery *itself* versus any mesh device that may be used during such surgery.

Plaintiffs do not challenge Dr. Bales's methodology as unreliable. Instead, Plaintiffs disagree with Dr. Bales's conclusions. Yet that is not a valid basis to exclude his opinions under *Daubert*, under which reliability depends "solely on principles and methodology, not on the conclusions that they generate." 509 U.S. at 595. Similarly, Plaintiffs' subjective belief that Dr. Bales "downplay[ed] significant complications" has no bearing in a *Daubert* analysis. *See* Pls.' Mem. (Dkt. 2057) at 8. Nor does Plaintiffs' inexplicable citation to their own deposition question constitute evidence of unreliability, particularly where they do not also include Dr. Bales's explanation on their claimed "dozens of articles that would say something differently." *See id.*

Dr. Bales logically explained: "I'm not sure they say anything a whole lot differently. There [are] papers that cite pain and dyspareunia after any type of vaginal surgeries . . . ." Ex. 2, Bales 4/1/16 Dep. Tr. 103:18-20. Plaintiffs' sleight of hand with the record is improper. Even so, to the extent Plaintiffs believe Dr. Bales inappropriately rejected scientific literature, as discussed above, these disagreements are appropriate for cross-examination, not a basis for exclusion.

At bottom, Dr. Bales has utilized a reliable basis for his opinion that dyspareunia is not a unique risk of Prolift and Gynemesh. This opinion therefore is admissible.

III. Dr. Bales's Opinion on Shrinkage Is Admissible Because He Utilized a Reliable Methodology.

Citing to the Dietz article, Dr. Bales opines that "[t]here is no medical literature conclusively establishing that mesh contracts with vaginal use to clinically significant degrees." Ex. A-1 to Pls.' Mot. (Dkt. 2054-2), Bales Report at 8. Dr. Bales's opinion differentiates between mesh contracture and scar formation, in which the scar—not the mesh—contracts. *Id.* at 8-9. Dr. Bales further explained that if mesh is placed in an appropriate tension-free setting, any mesh contracture—if it were to occur—likely would not be clinically noticeable. *Id*. On the other hand, if sub-optimally placed, then mesh contraction could conceivably cause complications. *Id*. These opinions are based on Dr. Bales's training, experience, and review of medical literature, which constitutes a reliable methodology.

Plaintiffs indeed do not challenge the methodology underlying Dr. Bales's opinion. They instead ask the Court to exclude opinions that Dr. Bales does not give, claiming that he concludes mesh shrinkage is "clinically insignificant" and "of no clinical importance." Pls.' Mem. (Dkt. 2057) at 9, 10. The Court need not address opinions that Dr. Bales never offered.

Even if Dr. Bales had given these opinions, Plaintiffs' argument that Dr. Bales ignored contrary evidence is nonetheless wrong. In each instance when they confronted him with allegedly contrary literature, he testified as to his consideration of the literature and rejection of Plaintiffs' counsel's attached significance. *See, e.g.*, Ex. 2, Bales 4/1/16 Dep. Tr. 86:19-90:21 (pointing out that the Jacquetin paper studied rats and that the author's conclusions concerning human implications were not clear), 112:18-116:9 (mentioning his disagreements with the study cited on page 9 of Plaintiffs' memorandum), 116:20-118:12 (explaining that the article is not clear if the pain was caused by contracture or other sources).[1]

Contrary to Plaintiffs' assertions, Dr. Bales explained the basis for his opinions on mesh contracture, including his assessment of the literature. In particular, the literature does not establish that the pain experienced by patients is caused by mesh contracture. *Id.* at 122:1-5. Similarly, mesh contracture has not been well-studied in the literature, and it is therefore not clear how much mesh contracts. *Id.* at 120:3-8.

Again, Plaintiffs' motion amounts to an attack on Dr. Bales's conclusions from his assessment of the literature, and years of surgical experience and training. Yet a disagreement with his conclusions cannot form the basis for exclusion under *Daubert*. Dr. Bales's testimony is admissible because it is grounded on a reliable methodology.

[1] The Cochrane Review did not study mesh contracture, and Plaintiffs merely cite their own reading of the paper into the deposition record while asking Dr. Bales if it was read correctly. Ex. 2, Bales 4/1/16 Dep. Tr. 108:1-18. Plaintiffs do not demonstrate how Dr. Bales failed to consider the Cochrane Review when he in fact relied upon it in his expert report. Ex. A-1 to Pls.' Mot. (Dkt. 2054-2), Bales Report at 8.

IV. Dr. Bales Is Qualified to Provide Opinions Concerning the Biocompatibility Properties of Pelvic Mesh.

A urologist is qualified by training and experience to provide opinions on the biocompatibility properties of pelvic mesh. *See, e.g. Mathison v. Boston Scientific Corp*., No. 2:13-CV-05851, 2015 WL 2124991, at *28 (S.D.W. Va. May 6, 2015). In *Mathison*, the plaintiffs sought to exclude the defendant's expert urologist from offering opinions relating to the physical properties of polypropylene, including shrinkage, contraction, and degradation, because the expert did not have pathology expertise. *Id*. The Court rejected the plaintiffs' argument, finding that the expert was qualified due to his experience performing thousands of sling procedures, and that the literature cited throughout his expert report supporting his opinion that the mesh was safe and effective. *Id*.

Here too, Dr. Bales has performed thousands of pelvic mesh procedures, and cites numerous articles and studies throughout his report demonstrating the safety and efficacy of Ethicon's mesh devices. *See, e.g*., Ex. A-1 to Pls.' Mot. (Dkt. 2054-2), Bales Report at 5-6 (Gynecare Prolift involved in over 100 studies), 17-18 (over 150 randomized controlled trials for TVT family of mesh devices). Thus, contrary to Plaintiffs' argument, Dr. Bales need not be a pathologist to render opinions on mesh biocompatibility. *See also Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 585 (S.D.W. Va. 2014), as amended (Oct. 29, 2014) (finding urologist with extensive pelvic-floor surgical experience qualified to offer opinions about mesh properties even though urologist was not a pathologist).[2]

[2] Even though Dr. Bales is not a pathologist, he is knowledgeable about pathology and has experience with histological review of specimens. *See* Ex. 2, Bales 4/1/16 Dep. Tr. 44:22-45:13.

Additionally, the precise opinions that Plaintiffs seek to exclude relate primarily to the *clinical* aspects of mesh biocompatibility. *See* Pls.' Mem. (Dkt. 2057) at 11. These clinical aspects fit exactly within the expertise of Dr. Bales, a surgeon who has performed thousands of pelvic surgeries with and without mesh, and treated patients of other surgeons experiencing complications. As this Court has recognized, an expert's own clinical observations serve as a valid basis to opine concerning alleged mesh defects. *Mathison*, 2015 WL 2124991, at *29. Further, "[o]ne knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an [expert] opinion." *Id*. at *28, citing *Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 799 (4th Cir. 1989).

Accordingly, Dr. Bales has the expertise required to provide opinions on the biocompatibility and inflammatory properties of Ethicon's mesh devices. This testimony is admissible.

V. Dr. Bales is Qualified to Opine on the Adequacy of the Warnings.

Dr. Bales bases his warnings opinions on his clinical experience, review of the medical literature, and statements of leading medical societies. Ex. A-1 to Pls.' Mot. (Dkt. 2054-2), Bales Report at 7-11, 19-23. Based on this support, Dr. Bales has formed the opinion that risks other than erosion and exposure—including dyspareunia, contraction, degradation, curling, pore collapse, cytotoxicity, inflammatory response, and cancer—either do not occur, or are known risks of pelvic surgery and not attributable to the mesh product. *Id.* Accordingly, Dr. Bales concludes that there are no additional unique risks that should be included in the mesh IFUs. *Id.* Dr. Bales's opinion is consistent with the legal principle that there is no duty to warn of risks commonly known to surgeons who use the device. 21 C.F.R. § 801.109(c) (information may be omitted from labeling for prescription device "if, but only if, the article is a device for which

directions, hazards, warnings and other information are commonly known to practitioners licensed by law to use the device.").

Based on his clinical perspective and review of the medical literature, Dr. Bales is qualified to give this opinion. He need not be familiar with FDA rules or regulations to give this testimony. *Winebarger*, 2015 WL 1887222, at *6-7, 15*; see also Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 703-04, 719 (S.D.W. Va. 2014) (Drs. Rosenzweig and Blaivas adequately experienced physicians to testify to risks of surgery and whether the risks were addressed in the IFU despite lack of expertise in FDA regulations or standards governing device warnings); *Trevino v. Boston Scientific Corp.*, 2:13-cv-01617, 2016 WL 1718836, at *13-14 (S.D.W. Va. Apr. 28, 2016) (Dr. Shull permitted to testify on adequacy of DFUs "from a clinical perspective"). Plaintiffs' arguments to the contrary should be rejected.

Dr. Bales does not offer his warnings opinions on the same basis as the physicians whose opinions were excluded in *Tyree* and *Bellew*. Nor have Plaintiffs alleged so. Those physicians offered opinions that the warnings were adequate merely because the warnings included risks that they observed in their own practices. *See Tyree*, 54 F. Supp. 3d at 584; *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Dkt. 265 at 33 (S.D.W. Va. Nov. 20, 2014).

Dr. Bales, however, bases his warnings opinions on his clinical experience, review of the medical literature, and statements of leading medical societies. Ex. A-1 to Pls.' Mot. (Dkt. 2054-2), Bales Report at 7-11, 19-23. While a single physician's experience may not be sufficient, it is sound methodology to rely upon a large pool of scientific literature and studies, combined with the clinical experience and evaluation of medical organizations, to support a conclusion that certain risks do not occur and therefore need not be included in the IFU, as Dr. Bales has done here. Indeed, when Plaintiffs' experts have concluded that risks do occur based on such support,

they are allowed to testify that the risk should have been included in the mesh warnings. It stands to reason that an expert employing this same methodology, while reaching a different conclusion, has also provided admissible testimony. That Plaintiffs may disagree with Dr. Bales's conclusion goes to weight, not admissibility.

At bottom, Dr. Bales is qualified to provide opinions on the IFUs and has employed a sufficiently reliable methodology. His opinion is therefore admissible.

VI. Plaintiffs Request to Limit Dr. Bales's Testimony in "Key Respects" Should Be Denied as Improper and Appropriately Handled by Cross-Examination.

To end their motion, Plaintiffs inappropriately ask the Court to limit or exclude Dr. Bales's opinions in two ways: (1) to the extent they are inconsistent or contrary to his deposition testimony, and (2) to render the opinions consistent with Plaintiffs' biased interpretation of his testimony. Both are improper. Plaintiffs should not assume that Dr. Bales will testify inconsistently with his deposition testimony. Even if he did, it is well-established that any inconsistencies should be addressed via cross-examination. *Sanchez*, 2014 WL 4851989, at *14.

Further, Plaintiffs provide no legal basis for the Court to limit Dr. Bales's opinions so that they conform with the Plaintiffs' subjective and inaccurate synopsis of select portions of his deposition testimony. In nearly every instance, Plaintiffs either misinterpret or unfairly confine Dr. Bales's testimony. For example, Dr. Bales testified that the IFU did not contain certain pieces of information, but he never stated that they were "inadequate." *See* Pls.' Mem. (Dkt. 2057) at 13. Plaintiffs' request that the Court filter Dr. Bales's testimony to align it with such a biased presentation of the evidence—or, worse, actually contradict his own stated opinions—lacks any legal basis whatsoever. Accordingly, Plaintiffs' request to limit the testimony in this manner should be rejected.

CONCLUSION

For the foregoing reasons, Ethicon respectfully requests that Plaintiffs' Motion to Exclude the General Opinion Testimony of Gregory T. Bales, M.D. be denied in its entirety.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on May 9, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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